

Remarks:

Applicants enclose a copy of the Notice of Improper Request for Continued Examination issued on May 17, 2006, as instructed by that Notice. Applicants hereby respond to that Notice by the timely submission of this Amendment in response to the Final Office Action of February 8, 2006 with an appropriate extension fee.

With this amendment, claims 1, 11, 12, 20, 23-64, 65-69 and 71-75 are pending in this application. Claims 2-9 had previously been cancelled. Claims 10, 13-19, 21, 23, 65 and 70 are cancelled and new claim 75-78 added herewith. All prior claims stand rejected by the Final Office Action of February 8, 2006.

The amended claims, and new claims 75-78, are presented in an effort to more clearly define Applicants' invention. Applicants believe the amended claims are allowable over the art of record. As amended, all pending claims are limited to clear or transparent propofol (2,6-diisopropylphenol) formulations of specific compositions in aqueous solutions with less than 15% excipients. The selection of specific compositions to produce injectable propofol, with minimal side effect-inducing excipients is achieved in accordance with the claimed invention by the specific combination, in limited amounts, of two specific solubilizing agents, polyethylene glycol and a block copolymer, particularly poloxamer 188. The known prior art references, taken either individually or collectively, do not show the claimed specific combinations, in the proportions claimed, to produce clear formulations, while at the same time keeping the total excipient concentration within desirable limits.

More specifically, while the prior art of record shows that numerous efforts have been made to provide an injectable propofol formulation with solubilizers like those used in the present invention, it fails to teach or to suggest specific combinations of those solubilizers and the limited amounts thereof which, when combined, does result in an injectable clear solution while maintaining the total excipient concentration within a desirable limit.

Applicants respectfully submit that the composition ranges recited in the amended claims define a sufficiently narrow range of subject matter that one skilled in the art can determine which formulations are clear to the naked eye while

maintaining the proportion of total excipients below 15% (w/v) and are therefore useful for the purposes of this invention.

Support for Applicants' position can be found throughout the specification, including but not limited to, Applicants' Table II located on page 35 of the specification as originally filed. That table is indicative that not all compositions, even within the limited range claimed by applicants, produce a clear solution. Nevertheless, Applicants' teaching is instructive as to the limited range of compositions which may be used to produce a clear, injectable composition with less than 15% total excipients. It is also indicative of the unlikelihood that the much broader ranges of compositions casually suggested in the prior art of record would permit those skilled in the art, by mere "optimization," to arrive at the very advantageous compositions taught and now claimed by Applicants.

For these reasons, Applicants believe the application is in condition for allowance. Notification to this effect is respectfully requested. The Examiner is invited to call Applicants' undersigned attorneys if it appears that further minor amendment or clarification may be necessary for allowance.

Respectfully submitted,



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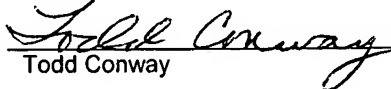
Enclosure: Notice of Improper Request for Continued Examination

Dated: July 10, 2006

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The Director is hereby authorized to charge or credit Deposit Account No. 18-0350 for any additional fees, or any underpayment or credit for overpayment in connection herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on: July 10, 2006


Todd Conway

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